

10-18-04

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TRANSMITTAL FORM

To be used for all correspondence
after initial filing)

Application Number	10/762,210
Filing Date	January 20, 2004
First Named Inventor	Ronald J. Berenson
Art Unit	1645
Examiner Name	
Attorney Docket No.	980034.417C5

ENCLOSURES (check all that apply)

<input type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Fee Attached <input type="checkbox"/> Amendment/Response <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input checked="" type="checkbox"/> Information Disclosure Statement; Form PTO-1449 (7 Sheets) <input type="checkbox"/> Cited References <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Response to Missing Parts under 37 C.F.R. 1.52 or 1.53 <input type="checkbox"/> Response to Missing Parts/Incomplete Application	<input type="checkbox"/> Drawing(s) <input type="checkbox"/> Request for Corrected Filing Receipt <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation, Change of Correspondence Address <input type="checkbox"/> Declaration <input type="checkbox"/> Statement under 37 CFR 3.73(b) <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund	<input type="checkbox"/> CD(s), Number of CD(s) _____ <input type="checkbox"/> After Allowance Communication to Technology Center (TC) <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to TC (<i>Appeal Notice, Brief, Reply Brief</i>) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input checked="" type="checkbox"/> Return Receipt Postcard <input type="checkbox"/> Additional Enclosure(s) (<i>please identify below</i>): _____ _____ _____
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Remarks

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Individual Name	Julie A. Urvater, Ph.D., Patent Agent Reg. No. 50,461	Customer Number 00500
Signature		
Date	October 15, 2004	

CERTIFICATE OF TRANSMISSION/MAILING

VIA EXPRESS MAIL

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.
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EXPRESS MAIL NO. EV449562705US

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Ronald J. Berenson et al.
Application No. : 10/762,210
Filed : January 20, 2004
For : ACTIVATION AND EXPANSION OF CELLS

Art Unit : 1645
Docket No. : 980034.417C5
Date : October 15, 2004

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents:

In accordance with 37 CFR 1.56 and 1.97 through 1.98, applicants wish to make known to the Patent and Trademark Office the references set forth on the attached Forms PTO-1449. This application is a continuation-in-part and relies, under 35 U.S.C. § 120, on the earlier filing date of prior U.S. Patent Application No. 10/350,305, filed January 22, 2003; which is a continuation-in-part of U.S. Patent Application No. 10/187,467, filed June 28, 2002; which is a continuation-in-part of U.S. Patent Application No. 10/133,236, filed April 26, 2002; which is a continuation-in-part of U.S. Patent Application No. 09/960,264, filed September 20, 2001; which is a continuation-in-part of U.S. Patent Application No. 09/794,230, filed February 26, 2001. The references listed on the attached Forms PTO-1449 were submitted to and/or cited by the Patent and Trademark Office in these prior applications and, therefore, are not required to be provided in this application. If the Examiner wishes, copies will be provided upon request.

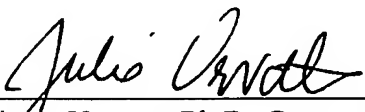
As to any reference previously supplied, applicants do not admit that it is "prior art" under 35 U.S.C. §§ 102 or 103, and specifically reserve the right to traverse or antedate any such reference, as by a showing under 37 CFR 1.131 or other method. Although the aforesaid references are made known to the Patent and Trademark Office in compliance with applicants' duty to disclose all information they are aware of which is believed relevant to the examination of the above-identified application, applicants believe that their invention is patentable.

Please acknowledge receipt of this Information Disclosure Statement and kindly make the cited references of record in the above-identified application.

Applicants believe this Information Disclosure Statement has been timely filed, however, the Director is authorized to charge any fee due by way of this Information Disclosure Statement to our Deposit Account No. 19-1090.

Respectfully submitted,

Seed Intellectual Property Law Group PLLC



Julie A. Urvater, Ph.D., Patent Agent
Registration No. 50,461

JAU:ljt

Enclosures:

Postcard
Transmittal Form
Form PTO-1449 (7 Sheets)

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FORM PTO-1449
(REV. 7-80)U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE

ATTY. DOCKET NO.

980034.417C5

APPLICATION NO.

10/762,210

INFORMATION DISCLOSURE STATEMENT

(Use several sheets if necessary)

APPLICANTS

Ronald J. Berenson et al.

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January 20, 2004

GROUP ART UNIT

1645

U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	AA	5,081,029	01/14/92	Zarling et al.	435	172.3	
	AB	5,190,878	03/02/93	Wilhelm	435	285	
	AC	5,443,983	08/22/95	Ochoa et al.	435	240.2	
	AD	5,470,730	11/28/95	Greenberg et al.	435	172.3	
	AE	5,674,704	10/07/97	Goodwin et al.	435	69.1	
	AF	5,735,279	04/07/98	Klaveness et al.	128	654	
	AG	5,804,442	09/08/98	Romet-Lemonne et al.	435	374	
	AH	5,858,358	01/12/99	June et al.	424	130.1	
	AI	5,888,807	03/30/99	Palsson et al.	435	293.2	
	AJ	5,962,319	10/05/99	Ogawa et al.	435	325	

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	TRANSLATION	
					YES	NO
	AK	EP 440373 B1	04/23/97	EPO		
	AL	EP 633930 B1	04/26/00	EPO		
	AM	WO 97/01304	01/16/97	WIPO		
	AN	WO 97/05233	02/13/97	WIPO		
	AO	WO 97/05239	02/13/97	WIPO		

OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)

	AP	"CD4+ T Cell Diversity Not Immediately Restored by Therapy," NIAID AIDS Agenda, August 1997, accessed on July 8, 2002. Available at http://www.niaid.nih.gov/publications/agenda/1097/page3.htm .
	AQ	Arenz, M. et al., "Antigen-independent in vitro expansion of T cells does not affect the T cell receptor V β repertoire," <i>J. Mol. Med.</i> 75: 678-686, 1997.
	AR	Baroja, M.L. et al., "The Anti-T Cell Monoclonal Antibody 9.3 (Anti-CD28) Provides a Helper Signal and Bypasses the Need for Accessory Cells in T Cell Activation with Immobilized Anti-CD3 and Mitogens," <i>Cellular Immunology</i> 120: 205-217, 1989.

EXAMINER

DATE CONSIDERED

* EXAMINER: Initial if reference considered, whether or not criteria is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant(s).

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(REV. 7-80)U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICEATTY. DOCKET NO.
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U.S. PATENT DOCUMENTS

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	BA	5,985,653	11/16/99	Armstrong et al.	435	303.1	
	BB	6,010,902	01/04/00	Ledbetter et al.	435	328	
	BC	6,096,532	08/01/00	Armstrong et al.	435	286.5	
	BD	6,113,901	09/05/00	Bluestone	424	154.1	
	BE	6,129,916	10/10/00	Chang	424	179.1	
	BF	6,143,297	11/07/00	Bluestone	424	184.1	
	BG	6,197,298	03/06/01	Chang	424	179.1	
	BH	6,316,257	11/13/01	Flyer et al.	435	372.3	
	BI	6,352,694	03/05/02	June et al.	424	93.71	
	BJ	6,355,779	03/12/02	Goodwin et al.	530	388.23	

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	TRANSLATION	
					YES	NO
	BK	WO 00/02520	01/20/00	WIPO		X
	BL	WO 00/02520	01/20/00	WIPO	X	
	BM	WO 03/024312	03/27/03	WIPO		
	BN	WO 03/025158	03/27/03	WIPO		
	BO	WO 03/034820	05/01/03	WIPO		

OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)

	BP	Bergstresser, P.R. et al., "T Cell-Mediated Terminal Maturation of Dendritic Cells," in <i>Dendritic Cell in Fundamental and Clinical Immunology</i> , Ricciardi-Castagnoli (Ed.), Plenum Press, New York, 1997, pgs. 65-69.
	BQ	Bonyhadi, M. et al., "Xcellerate: An Autologous T Cell Immunotherapy Approach for Treating B-Cell Lymphocytic Leukemia (B-CLL)," in <i>Proceedings of the 42nd Annual Meeting of the American Society of Hematology</i> , San Francisco, December 1-5, 2000, vol. 96, no. 11, part 1, ABSTRACT # 3616.
	BR	Bretscher, P., "The two-signal model of lymphocyte activation twenty-one years later," <i>Immunology Today</i> 13(2): 74-76, 1992.

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DATE CONSIDERED

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FORM PTO-1449
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PATENT AND TRADEMARK OFFICEATTY. DOCKET NO.
980034.417C5APPLICATION NO.
10/762,210**INFORMATION DISCLOSURE STATEMENT**
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APPLICANTS

Ronald J. Berenson et al.

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	CA	2001/0031253	10/18/01	Gruenberg	424	93.1	
	CB	2002/0090362	07/11/02	Strauss	424	93.21	
	CC	2002/0182730	12/05/02	Gruenberg	435	375	
	CD	2003/0039650	02/27/03	Gruenberg	424	144.1	
	CE	2003/0134341	07/17/03	Gruenberg	435	7.21	
	CF	2003/0134415	07/17/03	Gruenberg	435	372	
	CG	2003/0170238	09/11/03	Gruenberg	424	144.1	
	CH	2003/0175242	09/18/03	Gruenberg	424	93.2	
	CI	2003/0175272	09/18/03	Gruenberg	424	144.1	
	CJ	2003/0194395	10/16/03	Gruenberg et al.	424	93.7	

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	TRANSLATION	
					YES	NO
	CK	WO 03/043643	05/30/03	WIPO		
	CL	WO 03/077658	09/25/03	WIPO		
	CM					
	CN					
	CO					

OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)

	CP	Carlens, S. et al., "Ex vivo T lymphocyte expansion for retroviral transduction: Influence of serum-free media on variations in cell expansion rates and lymphocyte subset distribution," <i>Experimental Hematology</i> 28: 1137-1146, 2000.
	CQ	Chapman, A.L.N. et al., "Epstein-Barr Virus-specific Cytotoxic T Lymphocyte Responses in the Blood and Tumor Site of Hodgkin's Disease Patients: Implications for a T-cell-based Therapy," <i>Cancer Research</i> 61: 6219-6226, August 15, 2001.
	CR	Cohen, P.A. et al., "T-Cell Adoptive Therapy of Tumors: Mechanisms of Improved Therapeutic Performance," <i>Critical Reviews in Immunology</i> 21: 215-248, 2001.

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FORM PTO-1449 (REV. 7-80)	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY. DOCKET NO. 980034.417C5	APPLICATION NO. 10/762,210
INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)		APPLICANTS Ronald J. Berenson et al.	
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U.S. PATENT DOCUMENTS

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	DA						

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	TRANSLATION	
					YES	NO
	DB					

OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)

	DC	Creson, J. et al., "The Mode and Duration of Anti-CD28 Costimulation Determine Resistance to Infection by Macrophage-Tropic Strains of Human Immunodeficiency Virus Type 1 in Vitro," <i>Journal Of Virology</i> , 73(11):9337-9347, November 1999.
	DD	Dietrich, P-Y et al., "TCR analysis reveals significant repertoire selection during <i>in vitro</i> lymphocyte culture," <i>International Immunology</i> 9(8): 1073-1083, 1997.
	DE	Garland et al., "The use of Teflon cell culture bags to expand functionally active CD8 ⁺ cytotoxic T lymphocytes," <i>Journal of Immunological Methods</i> 227: 53-63, 1999.
	DF	Groh, V. et al., "Stimulation of T cell autoreactivity by anomalous expression of NKG2D and its MIC ligands in rheumatoid arthritis," <i>Proceedings of the National Academy of Sciences</i> 100(16): 9452-9457, August 5, 2003.
	DG	Haanen et al., "Selective Expansion of Cross-reactive CD8 ⁺ Memory T Cells by Viral Variants," <i>J. Exp. Med.</i> 190(9): 1319-1328, November 1, 1999.
	DH	Hami, L. et al., "Xcellerate™: A Platform Process for the GMP Manufacture of Activated T Cells for the Treatment of Patients with Cancer and Immune Dysfunction," in <i>Proceedings of the 42nd Annual Meeting of the American Society of Hematology</i> , San Francisco, December 1-5, 2000, vol. 96, no. 11, part 1, abstract # 3630.
	DI	Heitger, A. et al., "Defective T-helper cell function after T-cell-depleting therapy affecting naïve and memory populations," <i>Blood</i> 99(11): 4053-4062, June 2002.
	DJ	Husebekk, A. et al., "Selection and expansion of T cells from untreated patients with CLL: source of cells for immune reconstitution," <i>Cytotherapy</i> 2(3): 187-193, 2000.
	DK	Iezzi et al., "The Duration of Antigenic Stimulation Determines the Fate of Naive and Effector T Cells," <i>Immunity</i> 8: 89-95, January 1998.
	DL	Jason, J. et al., "The Effect of Mitogens, IL-2 and Anti-CD3 Antibody on the T-Cell Receptor Vβ Repertoire," <i>Scand. J. Immunol.</i> 43: 652-661, 1996.

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U.S. PATENT DOCUMENTS

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	EA						

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	TRANSLATION	
					YES	NO
	EB					

OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)

	EC	June et al., "The B7 and CD28 receptor families," <i>Immunology Today</i> 15(7): 321-331, 1994.
	ED	Kalamasz, D. et al., "Storage Shipment of Freshly Harvested or Cryopreserved Xcellerate™ Activated T Cells for Clinical Applications," in <i>Proceedings of the 42nd Annual Meeting of the American Society of Hematology</i> , San Francisco, December 1-5, 2000, vol. 96, no. 11, part 2, abstract # 5113.
	EE	Kato et al., "Gene Transfer of CD40-Ligand Induces Autologous Immune Recognition of Chronic Lymphocytic Leukemia B Cells," <i>J. Clin. Invest.</i> 101(5): 1133-1141, March 1998.
	EF	Kluin-Nelemans, H.C. et al., "Correction of Abnormal T-Cell Receptor Repertoire During Interferon- α Therapy in Patients With Hairy Cell Leukemia," <i>Blood</i> 91(11): 4224-4231, June 1998.
	EG	Krawczyk et al., "Cbl-b Is a Negative Regulator of Receptor Clustering and Raft Aggregation in T Cells," <i>Immunity</i> 13: 463-473, October 2000.
	EH	Lanzavecchia, A., "The Role of Dendritic Cells in the Generation of Effector and Memory T Cell Responses," from <i>The Midwinter Conference of Immunologists</i> , January 22-25, 2000, available at www.midwconfimmunol.org/Midwinter00/sessions/lanzavecchia.html .
	EI	Larsson, S. et al., "Productive Cytomegalovirus (CMV) Infection Exclusively in CD13-Positive Peripheral Blood Mononuclear Cells from CMV-Infected Individuals," <i>Transplantation</i> , 65(3):411-415, February 15, 1998.
	EJ	Levings, M.K. et al., "Human CD25 ⁺ CD4 ⁺ T regulatory cells suppress naive and memory T cell proliferation and can be expanded in vitro without loss of function," <i>J. Exp. Med.</i> 193(11): 1295-1301, June 2001.
	EK	Li, Q. et al., "Expanded Tumor-reactive CD4 ⁺ T-Cell Responses to Human Cancers Induced by Secondary Anti-CD3/Anti-CD28 Activation," <i>Clinical Cancer Research</i> 5: 461-469, February 1999.
	EL	Li, Q. et al., "Immunological Effects of BCG as an Adjuvant in Autologous Tumor Vaccines," <i>Clinical Immunology</i> 94(1): 64-72, January 2000.

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	FA						

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	TRANSLATION	
					YES	NO
	FB					

OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)

	FC	Liebowitz et al., "Costimulatory approaches to adoptive immunotherapy," <i>Current Opinion in Oncology</i> 10: 533-541, 1998.
	FD	Lin and Welsh, "Stability and Diveristy of T Cell Receptor Repertoire Usage during Lymphocytic Choriomenigitis Virus Infection of Mice," <i>Journal of Experimental Medicine</i> 188(11): 1993-2005, December 7, 1998.
	FE	Lopez, R.D. et al., "CD58/LFA-3 and IL-12 provided by activated monocytes are critical in the in vitro expansion of CD56 ⁺ T cells," <i>Cancer Immunol. Immunother.</i> 49: 629-640, 2001.
	FF	Mariani, S. et al., "Severe and long-lasting disruption of T-cell receptor diversity in human myeloma after high-dose chemotherapy and autologous peripheral blood progenitor cell infusion," <i>British Journal of Hematology</i> 113: 1051-1059, 2001.
	FG	Marijt and Falkenburg, "Specific T Cell Therapy in Leukemia," <i>Journal of Hematotherapy & Stem Cell Research</i> 10: 493-500, 2001.
	FH	Moebius, U. et al., "T cell receptor gene rearrangements of T lymphocytes infiltrating the liver in chronic active hepatitis B and primary biliary cirrhosis (PBC): oligoclonality of PBC-derived T cell clones," <i>Eur. J. Immunol.</i> 20: 889-896, 1990.
	FI	Nijhuis, M. et al., "Stochastic processes strongly influence HIV-1 evolution during suboptimal protease-inhibitor therapy," <i>Proc. Natl. Acad. Sci. USA</i> 95: 14441-14446, November 1998.
	FJ	Polanski, M. et al., "Xcellerate(: A Closed, Scalable Process for the GMP Manufacture of Stable Activated T Cells," in <i>Proceedings of the 15th Annual Scientific Meeting of the Society for Biological Therapy</i> , Seattle, October 26-29, 2000, and <i>Journal of Immunotherapy</i> , (23)5:599, September 2000.
	FK	Ranheim and Kipps, "Activated T Cells Induce Expression of B7/BB1 on Normal or Leukemic B Cells through a CD40-dependent Signal," <i>J. Exp. Med.</i> 177: 925-935, April 1993.
	FL	Ria, F. et al., "Molecular Characterization of the T Cell Repertoire Using Immuno-scope Analysis and its Possible Implementation in Clinical Practice," <i>Current Molecular Medicine</i> 1: 297-304, 2001.

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	GA						
FOREIGN PATENT DOCUMENTS							
		DOCUMENT NUMBER	DATE	COUNTRY		TRANSLATION	
						YES	NO
	GB						
OTHER ART <i>(Including Author, Title, Date, Pertinent Pages, Etc.)</i>							
	GC	Riddell, S.R. et al., "T-Cell Therapy of Leukemia," <i>Cancer Control</i> 9(2): 114-122, March/April 2002.					
	GD	Shimizu, N. et al., 'Large-Scale <i>ex Vivo</i> Expansion of Primary T Lymphocytes in Late-Stage AIDS Patients,' <i>AIDS Research and Human Retroviruses</i> 16(6): 611-612, 2000.					
	GE	Stohl, W. et al., "Polyclonal <i>in Vitro</i> T Cell Proliferation and T Cell-Dependent B Cell Differentiation Supported By Activated Autologous B Cells," <i>Clinical Immunology and Immunopathology</i> 72(1): 44-52, July 1994.					
	GF	Tao, Q. et al., "Conservation of Epstein-Barr Virus Cytotoxic T-Cell Epitopes in Posttransplant Lymphomas. Implications for Immune Therapy," <i>American Journal of Pathology</i> 160(5): 1839-1845, May 2002.					
	GG	Ten Berge et al., "Selective Expansion of a Peripheral Blood CD8 ⁺ Memory T Cell Subset Expressing Both Granzyme B and L-Selectin During Primary Viral Infection in Renal Allograft Recipients," <i>Transplantation Proceedings</i> 30: 3975-3977, 1998.					
	GH	Vathsala, A. et al., "Inhibition of Apoptosis in Anti-CD3-Treated Peripheral Blood Lymphocytes by Immunosuppressive Drugs," <i>Transplantation Proceedings</i> 32: 1992-1994, 2000.					
	GI	Yamada, O. et al., "Clonal T-cell proliferation causing pure red cell aplasia in chronic B-cell lymphocytic leukaemia: successful treatment with cyclosporine following <i>in vitro</i> abrogation of erythroid colony-suppressing activity," <i>British Journal of Haematology</i> 101: 335-337, 1998.					
	GJ	Zou, J.-P. et al., "Tumor-Bearing Mice Exhibit A Progressive Increase in Tumor Antigen-Presenting Cell Function and A Reciprocal Decrease in Tumor Antigen-Responsive CD4 ⁺ T Cell Activity," <i>The Journal of Immunology</i> 148(2): 648-655, January 15, 1992.					
	GK						
	GL						
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